REMARKS/ARGUMENTS

The Present Invention

The present invention relates to a pigmented cosmetic composition comprising a water-in-oil emulsion, in which the emulsion comprises (a) an oil phase; (b) an aqueous phase; (c) a pigment; (d) an emulsifier; and (e) a separation inhibitor comprising a silicone elastomer.

The Pending Claims

Claims 1, 7-9, 11-32, and 53-58 are currently pending. Reconsideration of the pending claims is respectfully requested.

Summary of the Office Action

Applicants gratefully acknowledge the withdrawal of the rejection of claims 1, 7-9, 11-32, and 53-58 over Hollenberg et al. (U.S. Patent No. 5,143,722) in view of Collin et al. (U.S. Patent No. 5,656,672) and Guthauser (U.S. Patent No. 5,162,378). The Office Action maintains the rejection of claims 1, 7-9, 11-32, and 53-58 under 35 U.S.C. § 103(a) as allegedly obvious over Stepniewski et al. (U.S. Patent No. 5,599,533) in view of Rapaport (U.S. Patent No. 5,730,991) and Dorogi et al. (U.S. Patent No. 5,882,661). In addition, claims 1, 7-9, 11-32, and 53-58 are rejected as allegedly obvious under 35 U.S.C. § 103(a) over Stepniewski et al. in view of Rapaport and Dorogi et al. and further in view of Collin et al.

Discussion of the Obviousness Rejections

A. Stepniewski et al. in view of Rapaport and Dorogi et al.

Stepniewski et al. allegedly discloses cosmetic compositions comprising water-in-oil emulsions comprising a silicone elastomer, a surfactant such as cetyl dimethicone copolyol, a water phase, a pigment, an oil phase, an inorganic salt, a stabilizer such as quaternium-18-hectorite, a thickening agent, a glycol, a sunscreening agent, and a preservative. Rapaport discloses a skin peel composition that can include octyl methoxycinnamate as a sunscreen agent. Dorogi et al. discloses a composition for treating or conditioning human skin, hair, or nails. The composition can include phenoxyethanol, propyl paraben, and methyl paraben as

preservatives. According to the Office Action, it would have been obvious to combine the elements disclosed by Rapaport and Dorogi et al. with the compositions taught by Stepniewski et al. in order to arrive at the instant invention. Specifically, the Office Action contends that since Stepniewski et al. describes using a surfactant in 0.01-20 wt% and also describes using a cetyl dimethicone copolyol, it would have been obvious to optimize this parameter to arrive at the limitation of 3-6 wt%.

The combination of Stepniewski et al., Rapaport, and Dorogi et al. does not render the present inventive compositions obvious. As stated in the Office Action, Rapaport and Dorogi et al. do not even mention the use of a cetyl dimethicone copolyol in any amount, let alone in the amount of about 3-6 wt%. Stepniewski et al. broadly describes the use of a surfactant in the range of about 0.01-20 wt%.

Applicant has unexpectedly discovered that adding about 3-6 wt% of a cetyl dimethicone copolyol emulsifier to the water-in-oil emulsion lends unusual stability to the present invention. The Office Action states that the previously submitted Rule 132 Declarations did not present a clear and convincing case for the unexpected stability of the inventive compositions over those in the prior art because the prior Declarations did not demonstrate the precise compositions tested. In response, Applicant submits a fourth Rule 132 Declaration summarizing the results of the three previous Rule 132 Declarations and describing the amounts of all ingredients in each formulation. Applicant believes that the current Declaration should clarify any unintended ambiguity in the previous Declarations. As seen in the current Rule 132 Declaration, compositions of the present invention comprising about 3-6 wt% cetyl dimethicone copolyol were stable for at least three months at 50 °C.

In contrast, compositions comprising a cetyl dimethicone copolyol emulsifier in an amount outside of the claimed range (e.g., comprising about 1 wt% and about 8 wt% cetyl dimethicone copolyol) were *not* similarly stable. Specifically, compositions comprising amounts of cetyl dimethicone copolyol outside of the claimed range are not stable for three month at 50 °C. Thus, even though Stepniewski et al. describes using a surfactant in the range of about 0.01-20 wt%, Applicant has shown that values *outside* of the claimed range (i.e., about 1 wt% and about 8 wt% cetyl dimethicone copolyol) but falling *within* the broad range of 0.01-20 wt%, do not provide a stable emulsion. Therefore, it cannot be said that

Stepniewski et al. renders the present invention obvious, since Stepniewski et al. clearly does not recognize any benefit in providing a composition comprising about 3-6 wt% of a cetyl dimethicone copolyol. Without any suggestion of improved stability, one of ordinary skill in the art would not have had any reasonable expectation of success that a composition comprising 3-6 wt% would have any surprising or unexpected properties. It is arguable that based on Stepniewski et al.'s disclosure, the ordinarily skilled artisan would be equally led to provide pigmented compositions comprising 1 wt% or 8 wt% cetyl dimethicone copolyol. However, as discussed above, compositions comprising cetyl dimethicone copolyol *outside* of the claimed range are not stable for 3 months at 50 °C. Therefore, it is only with the impermissible use of hindsight that one might allege that Stepniewski et al. teaches a composition of the present invention.

In view of the surprising and unexpected stability of the inventive composition and without a suggestion of how to modify the disclosure in the precise manner necessary to arrive at the present invention based on the disclosures of Stepniewski et al., Rapaport, and Dorogi et al., claims 1, 7-9, 11-32, and 53-58 are unobvious. Accordingly, the obviousness rejection in view thereof should be withdrawn.

B. Stepniewski et al. in view of Rapaport and Dorogi et al. and further in view of Collin et al.

As described above, Stepniewski et al. allegedly discloses cosmetic compositions comprising water-in-oil emulsions comprising an oil phase, an aqueous phase, a pigment, a cetyl dimethicone copolyol, and a silicone elastomer. Stepniewski et al. does not, however disclose that cetyl dimethicone copolyol should be used in about 3-6 wt%, as required by the pending claims, and which amount leads to surprising and unexpected stability of the inventive compositions. According to the Office Action, Rapaport and Dorogi et al. disclose compositions comprising octylmethoxycinnamate as a preferred sunscreen component, and phenoxyethanol, methyl paraben, and propyl paraben as preferred preservatives, respectively. The Office Action admits that Rapaport and Dorogi et al. do not provide motivation for the addition of cetyl dimethicone copolyol in an amount of about 3-6 wt%.

The pending claims are not obvious because one having ordinary skill in the art would not have been motivated to somehow combine the various disparate teachings of the cited

references and somehow arrive at the presently claimed composition. Collin et al. relates to maintaining stability and activity of retinol acne formulations with an organic solvent. Cetyl dimethicone copolyol is added as an emulsifier to the water-in-oil emulsion. Collin et al. reports that it is the organic solvent—and not the cetyl dimethicone copolyol—that stabilizes the retinol (col. 7, lines 33-40). Collin et al. does not teach or suggest that cetyl dimethicone copolyol provides any stability to the water-in-oil emulsion itself, as in the present invention.

Stepniewski et al. generally discloses compositions comprising a very broad range of 0.01-20 wt% of a long list of suitable surfactants (col. 4, lines 19-35). Stepniewski et al. does not recognize any perceived benefits of using cetyl dimethicone copolyol in 3-6 wt%. After reading Stepniewski et al., one of ordinary skill in the art would not appreciate that 3-6 wt% cetyl dimethicone copolyol, as opposed to any other of the numerous surfactants disclosed therein, lends any surprising stability to the emulsion. As a result, the ordinarily skilled artisan would not be pointed to the disclosure of Collin et al. since it pertains to maintaining retinol activity and not emulsion stability. There simply is no connector between the cited references that would lead one of ordinary skill in the art to provide the claimed composition. The rejection is thus unsupported factually and legally. "The motivation to combine references can not come from the invention itself." *Heidelberger Druckmaschinen AG v. Hantscho Commerical Prodcuts, Inc.*, 21 F.3d 1068, 30 U.S.P.Q.D.2d 1377 (Fed. Cir. 1993).

Moreover, "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability, this amounts to nothing more than impermissible hindsight." *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617. (Fed. Cir. 1999). Absent the teachings of the present application and the impermissible use of hindsight, in view of all of the literature available at the time of filing the present application, one of ordinary skill in the art would not be led to the disclosure of Collin et al.

Without motivation to combine references, the Office has not met its burden to establish a *prima facie* case of obviousness. Accordingly, the obviousness rejection in view of these references should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Date: August 9, 2006